

## **Section II (Remarks)**

### **A. Summary of Amendment to the Claims**

Claims 1 and 15-18 have been amended as set forth in the above Complete Listing of the Claims. As amended, the claims are supported by the specification and the original claims. No new matter has been added, as defined by 35 U.S.C. § 132.

Claims 1 and 18 have been amended to remove the recitation of particular properties of the PGA. Claims 15-17 have been amended to properly depend from claim 1.

Thus, upon entry of the amendments, claims 1, 2, and 4-20 will remain pending, of which claims 4-14, 19 and 20 are withdrawn.

In view of the finality of the December 18, 2009 Office Action and to ensure substantive consideration of this response, a Request for Continued Examination is concurrently submitted herewith, together with payment of the appertaining RCE fees (see *infra*, "CONCLUSION").

### **B. Rejection of Claims Under 35 U.S.C. §112**

In the Office Action mailed December 18, 2009 the examiner rejected claims 1 and 15-18 under 35 U.S.C. §112, second paragraph, as indefinite for recitation of "high" moisture absorbing properties, "high" moisture retaining properties, and "high" calcium solubility, recitation of "moisture absorbing properties," and "calcium solubility."

The examiner's attention is respectfully drawn to Section I above, where claims 1 and 15-18 have been amended to remove recitation of the term "high" in reference to the properties of the claimed PGA.

With regard to use of the terms the terms "moisture absorbing," "moisture retention" and "calcium solubility" in claims 15-17, it is well established that "[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of... [t]he content of the particular application disclosure... [and] t[he] claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made..." (MPEP 2173.02)

The examiner's attention is respectfully directed to Examples 1-4 of the application, where the "moisture absorbing," "moisture retention" and "calcium solubility" properties of the PGA are described. From this disclosure it would be clear to one of skill in the art that the percentages recited in claims 15-17 are relative to baseline measurements, as described in the Examples. The moisture absorption of claim 15 is relative to dried PGA. The moisture retention percentage of claim 16 is relative to water loss. The calcium solubility of claim 17 is relative to PGA with a molecular weight of less than 5,000.

As such, use of the terms "moisture absorbing," "moisture retention" and "calcium solubility" in claims 15-17 is clear and in compliance with the requirements of 35 U.S.C. § 112, second paragraph.

### **C. Rejection of Claims Under 35 U.S.C. §102**

In the Office Action mailed December 18, 2009, the examiner rejected claims 1-2 and 15-17 under 35 U.S.C. §102(b) as anticipated by PCT Publication No. WO 99/25864 (hereinafter "DiIorio et al."). Applicants respectfully traverse the rejection.

In the Response mailed September 10, 2009, applicants noted that the claimed PGA is isolated from *Bacillus subtilis* var. *chungkookjang* (KCTC0697BP) and that such manufacturing process steps impart distinctive structural characteristics to the final product. In response, the examiner argued that "applicants have provided no evidence to support this assertion..." (Office Action mailed December 18, 2009, p. 7.) It is the examiner's position that DiIorio et al. provide a  $\gamma$ -PGA "whose molecular weight is approximately 8,000,000 g/mol which corresponds to 8000 kDa..." and that DiIorio et al. therefore anticipate the claimed invention. Applicants respectfully disagree.

The examiner's attention is respectfully drawn to Exhibit A hereto, providing a comparison of the molecular weights of the  $\gamma$ -PGA obtained from each of *Bacillus licheniformis* (top) and *Bacillus subtilis* var. *chungkookjang* (bottom). As can be seen from the graphs, and from DiIorio et al., culture of *Bacillus licheniformis* initially results in a  $\gamma$ -PGA with a mean molecular weight of  $2.3 \times 10^6$  Da from the initial fermentation (DiIorio et al., p. 13, lines 11-12). This is represented in the graph in the upper left hand corner of Exhibit A. Clearly the  $\gamma$ -PGA initially produced from *Bacillus licheniformis* does not have a mean molecular weight in the high

molecular weight range, but provides a wide range of molecular weight  $\gamma$ -PGA with a lower mean. It is noted that Example I is titled simply "Production of  $\gamma$ -PGA."

In Example II of Dilorio et al., titled "Production of High Molecular Weight  $\gamma$ -PGA," the culture medium from Example I is fractionated, according to the methods of Examples VI and VII, in order to obtain the higher mean molecular weight  $\gamma$ -PGA, as represented in the graph in the upper right hand corner of Exhibit A. This additional fractionation step is required in order to obtain the higher mean molecular weight  $\gamma$ -PGA from the culture.

By contrast, as represented in the graph in the lower left hand corner of Exhibit A, a culture of *Bacillus subtilis* var. *chungkookjang* results in a  $\gamma$ -PGA with a mean molecular weight of 8,000-13,000kDa, as a result of the initial fermentation. Upon purification, a lower mean molecular weight  $\gamma$ -PGA can be obtained.

Therefore, contrary to the examiner's assertion, Dilorio et al. do not provide a  $\gamma$ -PGA equivalent to "[a]n ultra-high molecular weight poly-gamma-glutamate (PGA) having a mean molecular weight of at least 5,000 kDa and isolated from *Bacillus subtilis* var. *chungkookjang* (KCTC 0697BP)," where the  $\gamma$ -PGA cultured from *Bacillus licheniformis* requires fractionation in order to be within the high molecular weight range.

Since Dilorio et al. does not describe a PGA as set forth in claims 1-2 and 15-17, Dilorio et al. does not anticipate the claimed invention. Accordingly, withdrawal of the rejection of claims 1-2 and 15-17 under 35 U.S.C. § 102(b) as being anticipated by Dilorio et al. is respectfully requested.

#### **D. Rejection of Claims Under 35 U.S.C. §103**

Additionally in the Office Action mailed December 18, 2009 the examiner rejected claims 1 and 15-18 as obvious in view of Dilorio et al. Applicants respectfully disagree.

As set forth in detail above, Dilorio et al. does not anticipate claims 1 and 15-17, as Dilorio et al. do not provide a high mean molecular weight PGA from an initial culture of *Bacillus licheniformis*. The culture requires fractionation in order to obtain such a PGA with a high mean molecular weight.

The examiner cites Dilorio et al. at page 11, line 32 to page 12, line 5 as “teach[ing] a PGA whose molecular weight can rage [sic] from 2500 kDa to 100,000 kDa.” (Office Action mailed December 18, 2009, p. 6.) While the initial culture obtained from the *Bacillus licheniformis* provides a broad range of molecular weight, the mean molecular weight of such a culture is well below the high molecular weight range. The culture of Dilorio et al. requires fractionation before a PGA with a high mean molecular weight can be obtained.

The process of obtaining the claimed product is therefore superior to the process of Dilorio et al., where the initial culture of *Bacillus subtilis* var. *chunkookjang* is within the range of 8,000-13,000 kDa, and therefore there would have been no need for one of skill in the art to perform fractionation to obtain a high mean molecular weight PGA.

Based on the foregoing, Dilorio et al. fails to provide any logical basis for the PGA recited in claims 1 and 15-18. Dilorio et al. does not render the claimed invention obvious. Accordingly, withdrawal of the rejection of claims 1 and 15-18 under 35 U.S.C. § 103 (a) as being obvious over Dilorio et al. is respectfully requested.

### **CONCLUSION**

Based on the foregoing, all of applicants’ pending claims 1, 2 and 15-18 are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

The time for responding to the December 18, 2009 Office Action without extension was set at three months, or March 18, 2010. Applicants hereby request a three month extension of time under 37 CFR § 1.136 to extend the deadline for response to and including June 18, 2010. Payment of the extension fee of \$555.00 specified in 37 C.F.R. § 1.17(a)(3) and the RCE fee of \$405.00 specified in 37 C.F.R. § 1.17(e), as applicable to small entity, is being made by on-line credit card authorization at the time of EFS submission of this Response. Should any additional fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the examiner is requested to contact the undersigned attorneys at (919) 419-9350 to discuss same.

Respectfully submitted,

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